REMARKS

Upon entry of this amendment, claims 51-66 will be all the claims pending in this application. Claims 46-50 and 67-98 have been canceled and claims 51-66 have been amended.

Claims 51-54 have been amended to place the claims in independent form. In addition, claims 55-66 have been amended to replace "described" with --according to-- in the preamble, have been amended to prevent the claims from depending from a canceled claim, and have been amended for purposes of clarity.

Applicants respectfully submit that with the entry of the above amendments, the present application will be in condition for allowance.

Therefore, entry of the above amendments is respectfully requested.

Preliminarily, Applicants thank the Examiner for the personal interview held on November 6, 2002. Applicants believe that the interview materially advanced the prosecution of this case.

I. Response to rejection of Claims 51-98 Under 35 U.S.C. § 112, second paragraph

On pages 2-4 of the Office Action, the Examiner rejects claims 51-98 under 35 U.S.C. 112, second paragraph, as being indefinite.

A. According to the Examiner, claims 51-98 are indefinite because of the term "described" in line one of the claims.

Applicants have amended claims 55-98 by replacing "described in" with --according to--.

B. According to the Examiner, claims 51-54, 75-77 and 95-98 recite the limitation "the particles" or "the resultant particles" or "the average particle diameter".

The water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material comprise particles based on the various methods of producing the powdery composition of the present invention.

Accordingly, Applicants have amended the independent base claims to recite that the water-absorbing and water-insoluble base material and water-absorbing and gel-forming base material comprise particles. In addition, Applicants have amended the dependent claims by inserting --water-absorbing and water-insoluble-- and --water-absorbing and water-gel forming -- before "particles" for purposes of clarity.

With respect to the phrase "the average particle diameter", Applicants have replaced "the" with --an--.

With respect to "the resultant particles", Applicants have amended the claims by replacing "so that" with --to obtain a resultant water-absorbing and water-insoluble base material comprising water-absorbing and water-insoluble particles, wherein-- for purposes of clarity.

C. According to the Examiner claims 55, 56, 76, 77, 79, 80 and 95-98 are indefinite because it is unclear to which particles the claims are referring.

As noted above, Applicants have amended the claims by inserting the appropriate type of particle, i.e., water-absorbing and water-insoluble or water-absorbing and gel-forming, before "particles" for purposes of clarity.

D. According to the Examiner claims 58 and 82 are indefinite because it is unclear what Applicant intends by "vitamin preparations".

Applicants submit that one of skilled in the art would understand the meaning of "vitamin preparations". Particularly, at page 5, lines 42-43, the present specification discloses cyanocobalamin and mecobalamin as examples of vitamin preparations.

Therefore, Applicants submit that one of skill in the art would be apprised of the scope of the invention.

E. According to the Examiner claims 59, 61, 63, 83, 85 and 87 are indefinite because they recite the term derivatives.

In response, Applicants have changed the term "derivative" to "analog". Applicants submit that one skilled in the art would understand the meaning of the term "analog".

F. According to the Examiner, regarding claims 59, 63, 83 and 87, the phrase "insulin-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed.

As noted in the previous response, Applicants respectfully submit that the phrase "insulin-like growth factor" is a term of art that is well-known by one of skill in the art. Accordingly, Applicants re-submit herewith pages from *Products for Life Science Research* to support Applicants' position that the phrase "insulin-like growth factor" is a term of art. Accordingly, it is submitted that one of skill in the art would understanding the meaning and scope of the claims.

G. According to the Examiner, the term "vigorously" in claims 51, 68, 75 and 92 is a relative term that renders the claims indefinite.

At page 12, lines 9-19, the present specification discloses the difference between strongly (vigorously) and weakly mixing. Accordingly, it is submitted that one of skill in the art would understand the meaning of the term "vigorously", and therefore would be apprised of the scope of the invention. However, in view of the disclosure of "strongly" rather than "vigorously" in connection with the explanation at page 12, lines 9-19, Applicants have changed "vigorously" to "strongly". Further, in

view of the explanation of "strongly mixing" at page 12, lines 9-19, Applicants submit that one skilled in the art would understand what is meant by the term "strongly".

H. According to the Examiner, claim 54 are indefinite because it is unclear what part of the water-absorbing and gel-forming base material the average particle diameter of the water-absorbing and water-insoluble base material is larger than.

In the embodiments of the present invention according to claim 54, the average particle diameter of the water-absorbing and water-insoluble base material is larger than the average particle diameter of the water-absorbing and gel-forming base material. Therefore, although it is submitted that the scope of the claims are clear and one of skill in the art would understand the meaning of the claims, claims 54 and 78 have been amended by replacing "that of" with --an average particle diameter of-- to expedite prosecution.

In view of the above, Applicants respectfully request that the foregoing rejections be withdrawn.

II. Response to rejection of claims 46-57, 59-81 and 83-98 under 35 U.S.C. § 103(a)

On pages 5-7 of the Office Action, the Examiner rejects claims 46-57, 59-81 and 83-98 under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al.

Basically, the Examiner's position is substantially the same as that set forth in the previous Office Actions.

The Examiner continues to maintain that the declaration is not commensurate in scope with the instant independent claims. Additionally, the Examiner asserts that it is unclear how the AUC data provided in the declaration can be taken to show unexpected results of amount of drug adhered to the water-insoluble base. Also, the Examiner asserts that it is not clear how a greater adherence of the drug to the water-

insoluble base or an increased bioavailability of drug is unexpected over the prior art since Suzuki teaches both adherence of the drug to the water-insoluble base and that the water-insoluble base provides increased absorption efficiency of the drug through the nasal mucosa (col. 3, line 63 to col. 4, line 12).

Applicants respectfully traverse for the following reasons.

Initially, as noted in the previous responses, the Declaration was submitted to show that the compositions of Suzuki and the present invention are different (as a result of the processes used) and that because the compositions of Suzuki and the present invention are different, unexpected results are obtained by the present invention.

The Examiner believes that Suzuki discloses that the drug is dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material because Suzuki discloses that the drug is adhered to or dispersed in the water-absorbing and water-insoluble base material at col. 5, lines 53-66. However, the passage pointed out by the Examiner appears to be directed to a composition where only a water-absorbing and water-insoluble base material is used. Therefore, Applicants submit that the disclosure is not directed to a composition that contains a water-absorbing and water-soluble base material, and that when a water-absorbing and water-soluble base material is added, the drug adheres more to the water-absorbing and water-soluble base material.

In this regard, Applicants direct the Examiner's attention to the Declaration under 37 C.F.R. § 1.132 submitted previously to demonstrate the difference between the present invention and Suzuki, and that as a result, the present invention provides unexpectedly superior results.

As discussed in the Declaration, Suzuki discloses three methods for forming a

composition when a water-absorbing and water-soluble base material is used. First, at column 6, line 39-43, Suzuki discloses that "it may be admixed with polypeptide or its derivative and a water-absorbing and water-insoluble base in the mechanical mixing process, followed by the above-mentioned processes of compacting, etc." When the water-absorbing and water-insoluble base material and water-absorbing and water-soluble base material are mixed simultaneously, the strength of mixing influences the amount of drug that adheres to the water-absorbing and water-insoluble base. In order for more of the drug to adhere to the water-absorbing and water-insoluble base, strong mixing is required. However, Suzuki does not teach or suggest the strength of mixing.

Therefore, Suzuki does not teach or suggest a process of making a composition where more drug adhered to the water-absorbing and water-insoluble base material than on the water-absorbing and water-soluble base material. Therefore, the composition produced by the above Suzuki process is fundamentally different from the composition of the present invention

Second, at column 6, line 43-46, Suzuki discloses that "a water-absorbing and water-soluble base may be introduced into the process wherein polypeptide or its derivative is mixed with a water-absorbing and water-insoluble base in the presence of water." In the presence of water, the drug adheres more to the water-absorbing and water-soluble base because polypeptides drugs are hydrophilic and dissolve in water, and the water-absorbing and water-soluble base dissolves in water while the water-absorbing and water-insoluble base does not dissolve in water. Accordingly, the composition produced by this method does not have more drug adhered to the water-absorbing and water-insoluble base material than on or in the water-absorbing and water-soluble base material. Therefore, the composition produced by the above Suzuki process is fundamentally different from the composition of the present invention.

Third, at column 6, line 49-53, Suzuki discloses that "wherein a water-absorbing and water-soluble base is added to polypeptide or its derivative in the process in which polypeptide or its derivative is to be freeze-dried, thus both components being freeze-dried simultaneously as mentioned above." In this case, since the drug is freeze-dried with the water-absorbing and water-soluble base material, the drug adheres more to the water-absorbing and water-soluble base than on or in the water-absorbing and water-insoluble base material.

Therefore, the composition produced by the Suzuki process does not have more drug adhered to the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material.

The composition of the present invention has more drug adhered to the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material, and is obtained by the following methods.

1. The water-absorbing and water-insoluble base material and the drug are strongly mechanically mixed to obtain a mixture, and subsequently, the water-absorbing and gel-forming base material is mechanically mixed with the resultant mixture.

The composition of Example 73 was obtained by the above process, and the Cmax of Example 73 was 10.3 ng/ml. *See* pages 35-36 and Table 15 of the present specification. In contrast, the composition of Comparative Example 66 was obtained by a process of simply mixing the drug, water-absorbing and water-insoluble base material and water-absorbing and gel-forming base material in one step, and the Cmax of Example 66 was 5.1 ng/ml. Therefore, the composition of the present invention having more drug adhered to the water-absorbing and water-insoluble base material

obtained by the process of the present invention had a higher Cmax, which results in higher absorption.

2. The drug is adhered to the water-absorbing and water-insoluble base material by freeze drying, then, the water-absorbing and water-insoluble base material with the adhered drug is pulverized and sieved to obtain a resultant water-absorbing and water-insoluble base material comprising water-absorbing and water-insoluble particles, and subsequently, the water-absorbing and gel-forming base material is mechanically mixed with the resultant water-absorbing and water-insoluble base material.

The composition of Example 74 was obtained by the above process, and the Cmax of Example 74 was 10.7 ng/ml. *See* pages 35-36 and Table 15 of the present specification. In contrast, the composition of Comparative Example 67 was obtained by the process of Suzuki, and the Cmax of Comparative Example 67 was 5.7 ng/ml. Therefore, the composition of the present invention having more drug adhered to the water-absorbing and water-insoluble base material obtained by the process of the present invention had a higher Cmax, which results in higher absorption.

In addition, the present invention attains significantly higher amount of drug absorption and high maximum plasma concentration (Cmax) than the composition of Suzuki (as also shown in the Declaration under 37 C.F.R. § 1.132 submitted on March 14, 2001). Accordingly, the present invention provides unexpectedly superior results over Suzuki.

3. The drug and the water-absorbing and water-insoluble base material are dissolved or dispersed in an organic solvent to obtain a resultant solution or dispersion, and subsequently the resultant solution or dispersion is evaporated to obtain a powder, then the powder is pulverized and sieved to obtain a resultant

powder comprising water-absorbing and water-insoluble particles, and the water-absorbing and gel-forming base material is mechanically mixed with the resultant powder.

The composition of Example 77 was obtained by the above process, and the Cmax of Example 77 was 18.3 ng/ml. *See* pages 36-38 and Table 16 of the present specification. In contrast, the composition of Comparative Example 69 was obtained by dissolving or dispersing the drug in an organic solvent with the water-absorbing and gel-forming base material, and the Cmax of Comparative Example 69 was 3.6 ng/ml. Therefore, the composition of the present invention having more drug adhered to the water-absorbing and water-insoluble base material obtained by the process of the present invention had a higher Cmax, which results in higher absorption.

4. The average particle diameter of the water-absorbing and water-insoluble base material is larger than the average particle diameter of the water-absorbing and gel-forming base material.

The compositions of Examples 67 and 68 were obtained using particles where the average particle diameter of the water-absorbing and water-insoluble base material was larger than the average particle diameter of the water-absorbing and gel-forming base material, and the Cmax of Examples 67 and 68 were 13.8 ng/ml and 15.7 ng/ml, respectively. *See* pages 33-34 and Table 13 of the present specification. In contrast, the compositions of Comparative Examples 61 to 63 were obtained by using particles where the average particle diameter of the water-absorbing and water-insoluble - forming base material was not larger than the average particle diameter of the water-absorbing and gel-forming base material, and the Cmax of Comparative Examples 61 to 63 were 11.3 ng/ml, 6.6 ng/ml and 6.0 ng/ml, respectively. Therefore, the composition of the present invention having more drug adhered to the water-absorbing and water-

insoluble base material obtained by the process of the present invention had a higher Cmax, which results in higher absorption.

As shown by the above, the composition produced by the methods of the present invention are fundamentally different from compositions prepared by other methods, as can be seen from the difference in Cmax and AUC. Since the present invention possesses different properties from products made by different processes, the process limitations define the present invention.

Since the compositions of Suzuki and the present invention are fundamentally different and since the compositions are made by different processes, Applicants respectfully submit that the present invention is not obvious in light of Suzuki and that one of ordinary skill in the art would not expect the superior results of the present invention based on the disclosure of Suzuki. Accordingly, one of ordinary skill in the art would not be motivated to arrive at the present invention.

In view of the above, Applicants respectfully submit that Suzuki fails to teach or suggest the composition of the present invention, and respectfully requests that the foregoing rejection be withdrawn.

III. **Response to rejection of claims 58 and 82 under 35 U.S.C. § 103(a)**

On page 7 of the Office Action, the Examiner rejects claims 58 and 82 under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al., and further in view of Makino et al.

Basically, the Examiner's position is substantially the same as that set forth in the previous Office Actions.

Applicants respectfully submit that the claims should be allowed at least for the reason that Suzuki does not teach or suggest the present invention. In addition, Applicants submit that Makino does not teach or suggest a powdery composition

where a drug is unevenly dispersed on or in a water-absorbing and water-insoluble base material, and therefore, Suzuki in view of Makino fail to teach or suggest the present invention.

Accordingly, withdrawal of the foregoing rejection is respectfully requested.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 46-50 and 67-98 have been canceled.

The claims are amended as follows:

51. (amended) A powdery composition for nasal administration [described in Claim 46] comprising

(i) a drug,

(ii) one or more of a water-absorbing and gel-forming base material selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, hydroxyethyl cellulose, and sodium carboxymethyl cellulose and

(iii)one or more of a water-absorbing and water-insoluble base material selected from the group consisting of crystalline cellulose, α-cellulose, cross-linked sodium carboxy-methyl cellulose, cross-linked starch, chitin and chitosan,

wherein the content of the water-absorbing and gel-forming base material is about 5-40 wt% based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material,

70 wt % or more based on the drug is dispersed on or in the water-absorbing and water-insoluble base material and on or in the water-absorbing and gel-forming base material,

the water-absorbing and water-insoluble base material and water-absorbing and gel-forming base material comprise particles,

wherein [the state in which] the drug is [unevenly] dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material, and

wherein the powdery composition is [obtainable] obtained by a method comprising strongly mechanically mixing [that] the drug [is vigorously mechanically mixed] with the water-absorbing and water-insoluble base material to obtain a resultant mixture, in which at least 90 wt % based on the water-absorbing and water-insoluble particles have an average particle diameter in the range of 10-350 μm, and

subsequently, mechanically mixing the water-absorbing and gel-forming base material, in which at least 90 wt % based on the water-absorbing and gel-forming particles have an average particle diameter in the range of 10-350 μm, [is mechanically mixed] with the resultant mixture.

52. (amended) A powdery composition for nasal administration [described in Claim 46,] comprising

(i) a drug,

(ii) one or more of a water-absorbing and gel-forming base material selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, hydroxyethyl cellulose, and sodium carboxymethyl cellulose and

(iii)one or more of a water-absorbing and water-insoluble base material selected from the group consisting of crystalline cellulose, α-cellulose, cross-linked sodium carboxy-methyl cellulose, cross-linked starch, chitin and chitosan,

wherein the content of the water-absorbing and gel-forming base material is about 5-40 wt% based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material,

70 wt % or more based on the drug is dispersed on or in the water-absorbing and water-insoluble base material and on or in the water-absorbing and gel-forming base material,

the water-absorbing and water-insoluble base material and water-absorbing and gel-forming base material comprise particles,

wherein the drug is dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material, and

wherein the powdery composition is [obtainable] obtained by a method [that] comprising adhering the drug [is allowed to adhere] to the water-absorbing and water-insoluble base material by freeze drying,

then, pulverizing and sieving the water-absorbing and water-insoluble base material with the adhered drug [is pulverized and sieved so that] to obtain a resultant water-absorbing and water-insoluble base material comprising water-absorbing and water-insoluble particles, wherein at least 90 wt % based on the resultant water-absorbing and water-insoluble particles have an average particle diameter in the range of 10-350 μm, and

subsequently, mechanically mixing the water-absorbing and gel-forming base material, in which at least 90 wt % based on the water-absorbing and gel-forming particles have an average particle diameter in the range of 10-350 μm, [is mechanically mixed] with the resultant water-absorbing and water-insoluble base material.

53. (amended) A powdery composition for nasal administration [described in Claim 46, wherein] comprising

(i) a drug,

(ii) one or more of a water-absorbing and gel-forming base material selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, hydroxyethyl cellulose, and sodium carboxymethyl cellulose and

(iii)one or more of a water-absorbing and water-insoluble base material selected from the group consisting of crystalline cellulose, α-cellulose, cross-linked sodium carboxy-methyl cellulose, cross-linked starch, chitin and chitosan,

wherein the content of the water-absorbing and gel-forming base material is about 5-40 wt% based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material,

70 wt % or more based on the drug is dispersed on or in the water-absorbing and water-insoluble base material and on or in the water-absorbing and gel-forming base material,

the water-absorbing and water-insoluble base material and water-absorbing and gel-forming base material comprise particles,

wherein the drug is dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material, and

wherein the powdery composition is [obtainable] obtained by a method comprising [that] dissolving or dispersing the drug and the water-absorbing and water-insoluble base material [are dissolved or dispersed] in an organic solvent to obtain a resultant solution or dispersion, and

subsequently evaporating the resultant solution or dispersion [is evaporated such that] to obtain a powder [is obtained],

further pulverizing and sieving the powder [is pulverized and sieved such that] to obtain a resultant powder comprising water-absorbing and water-insoluble particles,

wherein at least 90 wt% based on the water-absorbing and water-insoluble [resultant] particles have an average particle diameter in the range of 10-350 μm, and

mechanically mixing the water-absorbing and gel-forming base material, in which at least 90 wt% based on the water-absorbing and gel-forming particles have an average particle diameter in the range of 10-350 μm, [is mechanically mixed] with the resultant powder.

54. (amended) A powdery composition for nasal administration [described in Claim 46,] comprising

(i) a drug,

(ii) one or more of a water-absorbing and gel-forming base material selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, hydroxyethyl cellulose, and sodium carboxymethyl cellulose and

(iii)one or more of a water-absorbing and water-insoluble base material selected from the group consisting of crystalline cellulose, α-cellulose, cross-linked sodium carboxy-methyl cellulose, cross-linked starch, chitin and chitosan,

wherein the content of the water-absorbing and gel-forming base material is about 5-40 wt% based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material,

70 wt % or more based on the drug is dispersed on or in the water-absorbing and water-insoluble base material and on or in the water-absorbing and gel-forming base material,

the water-absorbing and water-insoluble base material and water-absorbing and gel-forming base material comprise particles,

wherein [the state in which] the drug is dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material, and

wherein the powdery composition is [obtainable] obtained by a method comprising making [the] an average particle diameter of the water-absorbing and water-insoluble base material larger than [that] an average particle diameter of the water-absorbing and gel-forming base material.

55. (amended) A powdery composition for nasal administration [described in] according to claim 54, wherein the water-absorbing and water-insoluble base material has an average particle diameter of 10-350 μm in at least 90 wt % based on the water-absorbing and water-insoluble particles, and the water-absorbing and gel-forming base material has an average particle diameter of 10-105 μm in at least 90 wt % based on the water-absorbing and gel-forming particles.

56. (amended) A powdery composition for nasal administration [described in] according to claim 54, wherein the water-absorbing and water-insoluble base material has an average particle diameter of 10-250 μm in at least 90 wt % based on the water-absorbing and water-insoluble particles, and the water-absorbing and gel-forming base material has an average particle diameter of 10-65 μm in at least 90 wt % based on the water-absorbing and gel forming particles.

57. (amended) A powdery composition for nasal administration [described in] according to any one of Claims [46-47 and] 51-56, wherein the drug is selected from

the group consisting of non-peptide/non-proteinaceous drugs and peptide/proteinaceous drugs having molecular weight of 30,000 or less.

58. (amended) A powdery composition for nasal administration [described in] according to Claim 57, wherein the non-peptide/non-proteinaceous drug is one or more drugs selected from the group consisting of anti-inflammatory steroids, nonsteroidal anti-inflammatory drugs, analgesic anti-inflammatory agents, antitussive expectorants, antihistaminic agents, antiallergic drugs, antiemetic drugs, hypnotics, vitamin preparations, sex steroid hormones, antineoplastic drugs, antiarrhythmic drugs, antihypertensive drugs, antianxiety drugs, psychotropic drugs, antiulcer drugs, cardiotonics, analgesics, bronchodilators, treating agents for obesity, antithrombotic drugs, antidiabetic drugs, muscle relaxants and anti-rheumatics.

59. (amended) A powdery composition for nasal administration [described in] according to Claim 57, wherein the peptide/proteinaceous drug is one or more drugs selected from the group consisting of luteinizing hormone-releasing hormones, growth hormone-releasing factors, somatostatin [derivatives] analogs, vasopressins, oxytocins, hirudin [derivatives] analogs, enkephalins, adrenocorticotropic hormone [derivatives] analogs, bradykinin [derivatives] analogs, calcitonins, insulins, glucagon [derivatives] analogs, growth hormones, growth hormone-releasing hormones, luteinizing hormones, insulin-like growth factors, calcitonin gene-related peptides, atrial natriuretic polypeptide [derivatives] analogs, interferons, erythropoietin, granulocyte colony forming-stimulating factor, macrophage forming-stimulating factor, parathyroid hormones, parathyroid hormone-releasing hormone, prolactin, thyroid-stimulating hormone-releasing hormone and angiotensins.

60. (amended) A powdery composition for nasal administration [described in] according to any one of Claims [46-47 and] 51-56, wherein the drug is a peptide/proteinaceous drug having a molecular weight of 500-1500, and the amount of the water-absorbing and gel-forming base material is about 5-30 wt % based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material.

61. (amended) A powdery composition for nasal administration [described in] according to Claim 60, wherein the peptide/proteinaceous drug is one or more drugs selected from the group consisting of vasopressins, luteinizing hormone-releasing hormones, growth hormone-releasing factors, somatostatin [derivatives] analogs, oxytocins, hirudin [derivatives] analogs, enkephalins, adrenocorticotropic hormone [derivatives] analogs and bradykinin [derivatives] analogs.

62. (amended) A powdery composition for nasal administration [described in] according to any one of Claims [46-47 and] 51-56, wherein the drug is a peptide/proteinaceous drug having a molecular weight of 1500-30,000 and the amount of the water-absorbing and gel-forming base material is about 5-20 wt % based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material.

63. (amended) A powdery composition for nasal administration [described in] according to Claim 62, wherein the peptide/proteinaceous drug is one or more drugs selected from the group consisting of calcitonins, insulins, glucagon [derivatives]

analogs, growth hormones, growth hormone-releasing hormones, luteinizing hormones, insulin-like growth factors, calcitonin gene-related peptides, atrial natriuretic polypeptide [derivatives] analogs, interferons, erythropoietin, granulocyte colony-stimulating factor, macrophage-stimulating factor, parathyroid hormones, parathyroid hormone-releasing hormone, prolactin, thyroid-stimulating hormone-releasing hormone and angiotensins.

64. (amended) A powdery composition for nasal administration [described in] according to any one of Claims [46-47 and] 51-56, wherein the water-absorbing and water-insoluble base material is crystalline cellulose.

65. (amended) A powdery composition for nasal administration [described in] according to any one of Claims [46-47 and] 51-56, wherein the water-absorbing and gel-forming base material is hydroxypropyl cellulose.

66. (amended) A powdery composition for nasal administration [described in] according to Claim 65, wherein the hydroxypropyl cellulose has a viscosity of 150-4000 cps in 2% aqueous solution.